REMARKS

Claims 59-120 were pending. The U.S. Patent and Trademark Office alleges that claims 59-120 do not form a single inventive concept under PCT Rule 13.1 and MPEP 1875.01(d) [see PCT Article 17(3)(a) and 1.476(c)], and is requiring restriction of the claims. Applicants are canceling claims 59-120 and adding new claims 121-145 herein. Accordingly, claims 121-145 are pending and being examined.

New claims 121-145 do not involve new matter and are supported by the specification as originally filed. Entry of these amendments is respectfully requested.

Support for new claims 121 and 122 can be found in the originally-filed specification of the subject application at page 21, lines 24-29; page 22, lines 11-17; page 22, lines 26-31; page 23, lines 1-2 and lines 11-16 and lines 19-30; page 24, lines 1-9; and Figure 17A.

Support for new claim 123 can be found in the originally-filed specification of the subject application at page 16, lines 6-10.

Support for new claim 124 can be found in the originally-filed specification of the subject application at page 26, lines 1-20; and Appendix I at pages 107-113.

Support for new claim 125 can be found in the originally-filed specification of the subject application at page 22, lines 11-24; and page 26, lines 1-4.

Support for new claim 126 can be found in the originally-filed specification of the subject application at page 14, lines 24-25; and Figure 26.

Support for new claim 127 can be found in the originally-filed specification of the subject application at page 22, lines 13-17; and page 27, lines 13-24.

Support for new claim 128 can be found in the originally-filed specification of the subject application at page 28, lines 6-12; and page 97, lines 2-27.

Support for new claim 129-130 can be found in the originally-filed specification of the subject application at page 97, lines 2-27.

Support for new claim 131 can be found in the originally-filed specification of the subject application at page 14, line 27; and Figure 27.

Support for new claim 132 can be found in the originally-filed specification of the subject application at page 26, lines 15-20; page 58, lines 24-32; page 59, lines 1-7; page 63, lines 1-20; page 97, lines 2-27; page 98, lines 1-10; and Figure 9.

Support for new claim 133 can be found in the originally-filed specification of the subject application at page 27, lines 3-11; and Figure 25.

Support for new claim 134 can be found in the originally-filed specification of the subject application at page 17, lines 4-10.

Support for new claim 135 can be found in the originally-filed specification of the subject application at page 26, lines 1-20; and Appendix I at pages 107-113.

Support for new claim 136 can be found in the originally-filed specification of the subject application at page 16, lines 12-24.

Support for new claim 137 can be found in the originally-filed specification of the subject application at page 47, lines 19-21; and page 104, lines 12-19.

Support for new claim 138 can be found in the originally-filed specification of the subject application at page 30, line 30; and original claim 34.

Support for new claim 139 can be found in the originally-filed specification of the subject application at page 7, lines 18-21.

Support for new claim 140 can be found in the originally-filed specification of the subject application at page 25, lines 3-7.

Support for new claim 141 can be found in the originally-filed specification of the subject application at page 24, lines 11-13.

Support for new claim 142 can be found in the originally-filed specification of the subject application at page 22, lines 6-9.

Support for new claim 143 can be found in the originally-filed specification of the subject application at original claim 39.

Support for new claims 144-145 can be found in the originally-filed specification of the subject application at page 25, lines 9-19.

RESTRICTION REQUIREMENT

The Patent Office is requiring restriction to one of the following Groups of inventions:

Group I: claims 59-62, 65-75 and 118-119 are drawn to a first generation recombinant adenovirus in which a portion integrates into a host cell genome;

Group II: claims 63-64, 76-97 and 118-119 are drawn to a first generation recombinant adenovirus which targets a host cell of interest and a portion that integrates into the host cell genome;

Group III: claims 98-109 and 118-120 are drawn to a recombinant gutless adenovirus vector a portion of which integrates into a host cell genome;

Group IV: claims 110-114 are drawn to a method for producing a resolved gutless adenovirus vector via homologous recombination between two adenoviral vectors;

Group V: claims 115-116 are drawn to an adenovirus library comprising a plurality of adenovirus expressing fiber proteins displayed and modified by random peptide insertions; and

Group IV: claim 117 is drawn to screening methods for targeting adenovirus vectors for gene therapy comprising contacting a plurality of cells with an adenovirus library with fiber proteins displayed and modified by random peptide insertions.

ELECTION WITH TRAVERSE

Applicants hereby confirm election of the invention of Group II with traverse.

Reconsideration of the Restriction Requirement is requested for the following reasons.

The Patent Office alleges that, in accordance with PCT Rule 13.1, the special technical feature of the claims in Group I lack inventive step and does not make a contribution over the prior art in view of Wilson (U.S. Patent No. 5,856,152). Further, the Patent Office

alleges that since the claims of Group I lack novelty, then the subject matter of the claims of Groups I-VI will each be considered as the main invention and Groups I-VI do not form a single general inventive concept in accordance with PCT Article 17(3)(a) and 1.476(c).

THE CLAIMED INVENTION OF GROUP I IS INVENTIVE

The Patent Office alleges that the claimed invention of Group I (e.g., 59-62, 65-75 and 118-119) lacks inventive step in view of Wilson. Applicants respectfully disagree.

Applicants respectfully contend that the claimed invention of the claims in Group I is inventive because Wilson does not teach the recombinant adenoviral vectors comprising the elements in the order as claimed.

Applicants' Invention:

Applicants teach recombinant, double-stranded, hybrid Ad-AAV vectors, comprising on the first strand the following elements: a left and right Ad.ITR sequence; an Ad packaging sequence; a first and second AAV.ITR; a first and second IR sequence; a heterologous promoter; a foreign gene sequence; and a gene sequence that mediates replication of the adenovirus in a transduced cell. The second strand of the claimed vectors comprises a nucleotide sequence encoding a modified adenovirus fiber protein which alters the tropism of the adenovirus vector.

The art does not teach each and every element of the claimed vectors. The art vectors do not teach the same elements **AND** nucleotide sequences encoding modified adenovirus fiber proteins that alter the tropism of the adenovirus vector. Thus, the claimed vectors are inventive in view of the art vectors.

Wilson et al. (U.S. Patent No. 5,856,152):

Wilson teaches recombinant, hybrid Ad-AAV vectors comprising: a left and right Ad.ITR sequence; an Ad packaging sequence; a first and second AAV.ITR; a heterologous promoter sequence; an SV40 intron sequence; a foreign gene sequence; and a gene sequence that mediates adenoviral replication in a transduced cell (e.g., see vector pAd.AV.CMVLacZ in Figure 1A). However, Wilson does not teach any inverted repeat sequence or nucleotide sequences encoding modified adenovirus fiber proteins that alter the tropism of the adenovirus vector.

Wilson does not teach each and every element of the claimed invention. Thus, Wilson cannot anticipate the claimed adenoviral vectors.

The special technical features of the claims in Group I are both novel and inventive. Accordingly, the claimed invention meets the requirements of PCT Rule 13.1.

THE CLAIMED INVENTION FORMS A SINGLE GENERAL INVENTIVE CONCEPT

Applicants respectfully contend that the restriction requirement is improper because, as described above, the claimed invention has met the requirements of PCT Rule 13.1. Accordingly, the claimed invention forms a single, general inventive concept and therefore meets the requirements of MPEP 1875.01(d) [see PCT Article 17(3)(a) and 1.476(c)].

Applicants request the Patent Office to withdraw the restriction requirement.

Applicants point out that under MPEP §803, there are two criteria for a proper requirement for restriction, namely: (1) the invention must be independent and distinct; AND (2) there must be serious burden on the Examiner for restriction to be required.

Applicants respectfully contend that the first requirement of MPEP §803 has not been met, since the claims of Groups II-VI depend, directly or indirectly, upon the claims of Group I. Specifically, Applicants contend that the vectors of Group II are an embodiment of the vectors of Group I, since they both integrate into a host cell genome. Additionally, the vectors of Group II are used to produce the gutless vectors (Group III) and methods for producing the gutless vectors (Group IV). Additionally, the vectors of Group II are used to produce the display library of Group V which is in turn used in a method for screening adenoviral targeting vectors (Group VI). Therefore, the invention in Groups II, III, IV, V and VI are not independent and distinct. Accordingly, the criteria for requiring the restriction has not been met.

Applicants respectfully contend that the second requirement of MPEP §803 has also not been met. The Patent Office has not demonstrated a serious burden for searching the art of Groups I-VI. The Examiner can perform a search on the entire application without serious burden. Thus, search of the art with regard to the invention of Groups I-VI would not place an undue burden on the Examiner. Moreover, separate prosecution of these claims would be unnecessarily duplicative and thus wasteful of Patent Office resources. Therefore, under MPEP §803, the instant claims do not require restriction.

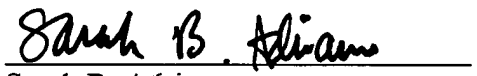
Applicants submit that claims of Groups I-VI should properly be examined together for the reasons discussed above. Applicants respectfully request that the Examiner reconsider and withdraw the Restriction Requirement as these claims.

CONCLUSION

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

No fee, other than the fee for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. If any additional fee is necessary, the Patent Office is authorized to charge any additional fee to Deposit Account No. 50-0306.

Respectfully submitted,



Sarah B. Adriano
Registration No. 34,470
Roberta D. German
Registration No. 43,902
Mandel & Adriano
55 So. Lake Ave., Suite 710
Pasadena, California 91101
626/395-7801
Customer No: 26,941